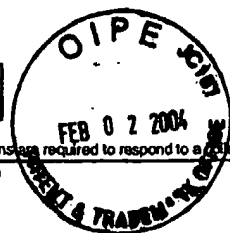


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**Complete if Known**

Application Number

10/613.975

**Filing Date**

**July 3, 2003**

**First Named Inventor**

**Donald L. Wise**

## Group Art Unit

1642

**Examiner Name**

Attorney Docket Number

CS 130

Sheet

1

**of**

8

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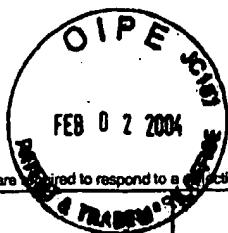
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		Filing Date	July 3, 2003
		First Named Inventor	Donald L. Wise
		Group Art Unit	1642
		Examiner Name	
Sheet 2 of 8	Attorney Docket Number	CSI 130	

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KS		ALONSO, et al., "Determinants of release rate of tetanus vaccine from polyester microspheres," <i>Pharm. Res.</i> 10(7): 945-953 (1993).	
		ANCHORDOQUY & KOE, "Physical stability of nonviral plasmid-based therapeutics," <i>J. Pharm. Science.</i> 89(3): 289-296 (2000).	
		ARORA & LEPPLA, "Residues 1-254 of anthrax toxin lethal factor are sufficient to cause cellular uptake of fused polypeptides," <i>J. Biol. Chem.</i> 268: 3334-3341 (1993).	
		BENNS & KIM, "Tailoring new gene delivery designs for specific targets," <i>J. Drug Target.</i> 8(1): 1-12 (2000).	
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KS		DENNIS, et al., "Tularemia as a biological weapon," <i>JAMA</i> 285(21): 2763-2773 (2001).	

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✓		DOOLAN, et al., "Circumventing genetic restriction of protection against malaria with multigene DNA immunization: CD8 <sup>+</sup> T cell-, Interferon $\gamma$ -, and nitric oxide-dependent immunity," <i>J. Exp. Med.</i> 183: 1739-1746 (1996).	
		DUESBERY, et al., "Proteolytic inactivation of MAP-kinase-kinase by anthrax lethal factor," <i>Science</i> 280: 734-737 (1998).	
		ELDRIDGE, et al., "Biodegradable and biocompatible poly(DL-lactide-co-glycolide) microspheres as an adjuvant for staphylococcal enterotoxin B toxoid which enhances the level of toxin-neutralizing antibodies," <i>Infect. Immunity</i> . 59: 2978-2986 (1991).	
		ELKINS, et al., "Rapid generation of specific protective immunity to <i>Francisella tularensis</i> ," <i>Infect. Immun</i> 60(11): 4571-4577 (1992).	
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		EL-MADHUN, et al., "Systemic and mucosal immune responses in young children and adults after parenteral influenza vaccination," <i>J. Infect. Dis</i> 178(4): 933-939 (1998).	
		ERMAK, et al., "Uptake and transport of copolymer biodegradable microspheres by rabbit Peyer's patch M cells," <i>Cell Tiss. Res.</i> 279: 433-436 (1995).	
		GARDNER, et al., "Chromosome 2 sequence of the human malaria parasite <i>Plasmodium falciparum</i> ," <i>Science</i> 282: 1126-1132 (1998).	
✓		GILLEY, et al., "Microencapsulation and its application to vaccine development," <i>Proc. 19<sup>th</sup> Int. Symp. Control. Rel. Bioact. Mater.</i> 19: 110-111 (1992).	

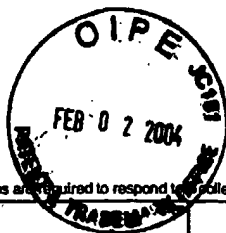
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		Filing Date	July 3, 2003
		First Named Inventor	Donald L. Wise
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		Examiner Name	
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km		GORDON, et al., "Proteolytic activation of bacterial toxins by eukaryotic cells is performed by furin and by additional cellular proteases," <i>Infect. Immun</i> 63: 82-87 (1995).	
		GU, et al., "Protection against anthrax toxin by vaccination with a DNA plasmid encoding anthrax protective antigen," <i>Vaccine</i> 17: 340-344 (1999).	
		GUPTA, et al., "Involvement of residues 147VYYEIGK153 in binding of lethal factor to protective antigen of <i>Bacillus anthracis</i> ," <i>Biochem. Biophys. Res. Commun.</i> 280: 158-163 (2001).	
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		HOFFMAN, et al., "Toward clinical trials of DNA vaccines against malaria," <i>Immun. Cell Biol.</i> 75: 376-381 (1997).	
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		KAWABATA, et al., "The fate of plasmid DNA after intravenous injection in mice: involvement of scavenger receptors in its hepatic uptake," <i>Pharm. Res.</i> 12(6): 825-830 (1995).	

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Application Number	10/613,975
Filing Date	July 3, 2003
First Named Inventor	Donald L. Wise
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Sheet	5	of	8
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km		KLIMPEL, et al., "Anthrax toxin protective antigen is activated by a cell surface protease with the sequence specificity and catalytic properties of furin," <i>Proc. Natl. Acad. Sci., USA</i> 89: 10277-10281 (1992).	
		KLINMAN, et al., "Repeated administration of synthetic oligodeoxynucleotides expressing CpG motifs provides long-term protection against bacterial infection," <i>Infect. Immunol.</i> 67: 5658-5663 (1999).	
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		LE, et al., "Safety, tolerability and humoral immune responses after intramuscular administration of a malaria DNA vaccine to healthy adult volunteers," <i>Vaccine</i> 18: 1893-1901 (2000).	
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		LITTLE & KNUDSON, "Comparative efficacy of <i>Bacillus anthracis</i> live spore vaccine and protective antigen vaccine against anthrax in the guinea pig," <i>Infect. Immun.</i> 52(2): 509-512 (1986).	

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✓		LUNSFORD, et al., "Tissue distribution and persistence in mice of plasmid DNA encapsulated in a PLGA-based microsphere delivery vehicle," <i>J. Drug. Target.</i> 8(1): 39-50 (2000).	
		LUO, et al., "Synthetic DNA delivery systems," <i>Nature Biotech</i> 18: 33-37 (2000).	
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		O'HAGAN, et al., "Long-term antibody response in mice following subcutaneous immunization with ovalbumin entrapped in biodegradable microparticles," <i>Vaccine</i> 11(9): 965-969 (1993).	
		PARTIDOS, et al., "Mucosal immunization with a measles virus CTL epitope encapsulated in biodegradable PLG microparticles," <i>J. Imm. Meth.</i> 195: 135-138 (1996).	
✓		PEREZ, et al., "Poly(lactic acid)-poly(ethylene glycol) nanoparticles as new carriers for the delivery of plasmid DNA," <i>J. Control. Rel.</i> 75: 211-224 (2001).	

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		PRICE, et al., "Protection against anthrax lethal toxin challenged by genetic immunization with a plasmid encoding the lethal factor protein," <i>Infect. Immunity</i> 69(7): 4509-4515 (2001).	
		SEDEGAH, et al., "Boosting with recombinant vaccinia increases immunogenicity and protective efficacy of malaria DNA vaccine," <i>Proc. Nat. Acad. Sci. USA</i> 95: 7648-7653 (1998).	
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		STOUTE, et al., "A preliminary evaluation of a recombinant circumsporozoite protein vaccine against <i>Plasmodium falciparum</i> malaria," <i>N. Engl. J. Med.</i> 336: 86-91 (1997).	
		THOMASIN, et al., "Tetanus toxoid and synthetic malaria antigen containing poly(lactide)/poly(lactide-co-glycolide) microspheres: importance of polymer degradation and antigen release for immune response," <i>J. Control. Rel.</i> 41: 131-145 (1996).	
		TINSLEY-BROWN, et al., "Formulation of poly (D,L-lactide-co-glycolic acid) microparticles for rapid plasmid DNA delivery," <i>J. Control. Rel.</i> 66: 229-241 (2000).	
✓		TRANTOLO, et al., "Delivery of vaccines by biodegradable polymeric microparticles with bioadhesion properties," <i>Proc. 5<sup>th</sup> World Congress, Chem. Eng.</i> (1996).	

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<p>Substitute for form 1449A/PTO</p> <p><b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b></p> <p>(use as many sheets as necessary)</p>		<b>Complete If Known</b>			
		Application Number	10/613,975		
		Filing Date	July 3, 2003		
		First Named Inventor	Donald L. Wise		
		Group Art Unit	1642		
		Examiner Name			
Sheet	8	of	8	Attorney Docket Number	CSI 130

OTHER ART - NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
V		VISSCHER, et al., "Biodegradation of and tissue reaction to 50:50 poly(DL-lactide-co-glycolide) microcapsules," <i>J. Biomed. Mat. Res.</i> 19: 349-365 (1985).	
		WANG, et al., "Simultaneous induction of multiple antigen-specific cytotoxic T lymphocytes in nonhuman primates by immunization with a mixture of four <i>Plasmodium falciparum</i> DNA plasmids," <i>Infect. Immunity</i> 66(9): 4193-4202 (1998).	
		WEINER, "Oral tolerance," <i>Proc. Natl. Acad. Sci. USA</i> 91: 10762-10765 (1994).	
		WOLFF, et al., "Direct gene transfer into mouse muscle in vivo," <i>Science</i> 247: 1465-1468 (1990).	
		WU & RUSSELL, "Nasal lymphoid tissue, intranasal immunization, and compartmentalization of the common mucosal immune system," <i>Immunol. Res.</i> 16(2): 187-201 (1997).	
		YEE, et al., "Loss of either CD4 <sup>+</sup> or CD8 <sup>+</sup> cells does not affect the magnitude of protective immunity to an intracellular pathogen, <i>Fancisella tularensis</i> strain LVS," <i>J. Immunol.</i> 157: 5042-5048 (1996).	

Examiner's Signature		Date Considered	6/14/05
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